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January 28, 2004

The Honorable Tommy Thompson
Secretary
Department of Health and Human Services
200 Independence Ave., S.W.
Washington D.C. 20201

Re: Release of ritonovir patents under Bayh-Dole due to
anticompetitive practices for NIH developed pharmaceutical

Dear Secretary Thompson:

I am writing to express my concern regarding the recent 500% price increase for the AIDS drug Norvir, (ritonavir) a protease inhibitor produced by Abbott Laboratories. As the largest AIDS organization in the United States, caring for over 12,000 patients in California, Florida, and New York, AIDS Healthcare Foundation is writing on behalf and in support of Essential Medicines, Inc., to request that you exercise the US government right (pursuant to the Bayh-Dole Act) to issue licenses to third parties for generic manufacture of ritonovir.

As you know, Norvir is an antiretroviral medication that is used in combination with other medications to suppress the HIV virus. Norvir is rarely used as the sole protease inhibitor in combination antiretroviral therapy because the required dosage, 600 mg, is generally poorly tolerated. However, it is frequently prescribed in smaller doses (100 mg or 200 mg) to boost the effectiveness of other protease inhibitors, including Fortovase (a Roche drug), Crixivan (a Merck drug), Agenerase (a GlaxoSmithKline drug), and Invirase (also a Roche drug, similar to Fortovase). According to the Seattle Times, about 80% of antiretroviral regimens contain Norvir. In addition, Invirase is clinically not recommended to be prescribed *without* a small dose of Norvir, because the Norvir assists with the absorption of Invirase. Ritonovir is an ingredient, along with another protease inhibitor, lopinivir, in Abbott's drug, Kaletra.

With the December price increase, the cost of a typical one day supply (100mg) has grown from \$1.17/day to \$8.50/day. This makes a ritonovir-containing regimen much more expensive, *unless* Abbott's Kaletra is used. Abbott has not increased the price of Kaletra. While Abbott has claimed that the price Norvir increase is necessary to fund an upcoming reformulation, it is our contention that the increase is a ploy to force patients off their current regimens and on to Kaletra. This

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AIDS HEALTHCARE FOUNDATION

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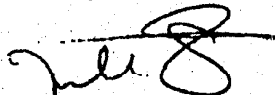
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aggressive and anticompetitive move will dramatically increase the price of non-Abbott protease inhibitor regimes that are used with ritonavir as a booster. The price increases for ritonavir and the aggressive pricing for other ARV drugs such as T-20, are placing enormous pressure on third party payers and patients.

Norvir has been available for retail since 1996, making it one of the older available protease inhibitors. Over 20,000 people in the U.S. depend on Norvir, in various combinations recommended by their physicians, for their continued health and well-being. This drastic increase in price is completely unjustified.

Because of Abbott's anticompetitive action and because that substantial NIH funding was used in the development of ritonavir, we urge you to issue a third party patent to Essential Medicines, inc.

Sincerely,



Michael Weinstein
President